DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 8, 2014

Gallini Medical Devices, Srl
% Mr. Authur S. Goddard
FDA Regulatory and Quality Systems Consultant
1531 Felton Road
South Euclid, Ohio 44121

Re: K141557
Trade/Device Name: Herniatome Percutaneous Discectomy Device
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 4, 2014
Received: November 7, 2014

Dear Mr. Goddard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K141557

Device Name: Herniatome Percutaneous Discectomy Device

Indications For Use:

The Herniatome Percutaneous Discectomy Device is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510k) Summary

The Summary of Safety and Effectiveness information on the Herniatome product is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

I. SUBMITTER

Applicant	Gallini Medical Devices, Srl Via Frattini, 15 46100 Mantova, Italy
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Date Prepared:	June 6, 2014

II. DEVICE

Name	Herniatome Percutaneous Discectomy Device
Common Name:	Percutaneous Discectomy Probe
Classification Name:	Arthroscope, 21 CFR 888.1100
Regulatory Class:	Class II
Product Code:	HRX

III. PREDICATE DEVICE

Predicate:	Stryker Instruments, Dekompressor™ Percutaneous Discectomy Probe, K032473, market clearance date November 7, 2003.
	No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Description:	The Herniatome Percutaneous Discectomy Kit is comprised of an Introducer needle and a Herniatome Percutaneous Discectomy Device. The Herniatome Percutaneous Discectomy Device is a single-use disposable discectomy device that is designed to remove intervertebral disc nucleus pulpous material under CT and fluoroscopic guidance. Radiopaque marker bands are located on the Introducer needle and the Herniatome Percutaneous Discectomy Device. The Herniatome Percutaneous Discectomy Device contains a battery source DC motor that causes the internal double pitch mechanism to act as a screw conveyor to retrieve and remove the excised debris through the outer cannula and into the transparent collection container. The Herniatome Percutaneous Discectomy Device is provided in two base models, a curved or straight distal end cannula with a lateral window and each model is provided with two different gage cannulas and two different cannula lengths for utilization in the specific region of the spine.
Associated Accessories:	Introducer Needle

Section 5: 510k) Summary

IV. DEVICE DESCRIPTION, continue

Models:

Cervical Herniatome

Product Code	Size	Description
DS17-09	17ga – 9cm	Curved distal end with lateral window
DS17-49	17ga – 9cm	Straight distal end with lateral window

Lumbar Herniatome

Product Code	Size	Description
DS17-15	17ga – 15cm	Curved distal end with lateral window
DS17-45	17ga – 15cm	Straight distal end with lateral window

Associated Accessories:

Introducer Needle

Product Code	Size	Description
DS 17/15	20 gage 22 cm	Introducer Needle

Sterilization: The method used is based on practices recommended by ISO 11135 and provides a Sterility Assurance Level (SAL) of 10^{-6}

V. INDICATION FOR USE

Intended Use: The Herniatome Percutaneous Discectomy Device is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTIC WITH PREDICATE DEVICE

Substantial Equivalency Information: Percutaneous discectomy is the technological principle for both the subject and predicate device. Discography is performed to confirm the targeted disc-radiated conflict. A cannula and stylet are guided into the target disc under CT and fluoroscopic guidance. The stylet is removed and the Herniatome is advanced into the targeted disc-radiated conflict. Once activated the Herniatome is used to aspirate the disc material in the lumbar, thoracic, and cervical regions of the spine. The Herniatome and predicate device are based on the following technological elements:

- Single-use disposable discectomy device
- Target Anatomy: Cervical, thoracic and lumbar spinal segments
- Configuration: Straight and curved
- Power: DC motor
- Mechanic of Action: Augur style mechanism to retrieve and remove the excised matter
- Patient contact material: biocompatible stainless steel

Section 5: 510k) Summary

VII. PERFORMACE DATA

Biocompatibility:

The Herniatome Percutaneous Discectomy Device produced by Gallini Medical Products was assessed against the International Standard ISO 10993-1, "*Biological evaluation of medical devices. Part 1. Guidance on selection of tests.*" The Herniatome would be classified as an External Communicating Device in contact with Tissue/Bone/Dentin Communicating for a Limited Duration (<24 hours). The battery of testing include the following tests:

Test	Standard
Cytotoxicity	ISO 10993-5
Maximum Sensitization – sodium chloride	ISO 10993-10
Maximum Sensitization – sesame oil	ISO 10993-10
Intracutaneous Reactivity	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11

Electrical Safety and Electromagnetic Compatibility:

Electrical Safety and Electromagnetic Compatibility that were performed on the Herniatome Percutaneous Discectomy Device in accordance with IEC 60601-1 standards for safety and the IEC 60601-1-2. Standard for Electromagnetic Compatibility.

Performance Testing:

The Herniatome Percutaneous Discectomy Device successfully passed all of the following performance tests:

Herniatome Percutaneous Discectomy Device Performance Testing
Accelerated Aging Shelf Life Package Testing
3-year Real Time Aging Battery Life Testing
Electromagnetic Compatibility and Electrical Safety
Radiodetectability
Technical Characteristic Performance Volume Flow Rate Study

Shelf Life:

In accordance with ISO 11607 the real time three year aging of Herniatome Percutaneous Discectomy Device demonstrated that the performance of the device met the standard requirements without any significant difference to product performance requirements before aging. So the product is stable and reliable within the three-year useful life.

Software Verification and Validation Testing:

The Herniatome Discectomy Device does not contain any software.

Animal Studies:

The Herniatome Percutaneous Discectomy Device did not conduct any performance testing on animals.

Clinical Studies:

The Herniatome Percutaneous Discectomy Device did not conduct any clinical testing.

Section 5: 510k) Summary

VII. CONCLUSION

Conclusion:	The information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Herniatome Percutaneous Discectomy Kit supports a determination of substantially equivalent to existing legally marketed predicate device Dekompressor™ Percutaneous Discectomy Probe, K032473. Any technological differences between the Herniatome Percutaneous Discectomy Kit and the predicate Stryker Instruments, Dekompressor™ Percutaneous Discectomy Probe, K032473 System device do not raise new questions of safety or effectiveness.